

**INFORMATION AND ASSENT FORM**  
Ages 7-11

**Study Name:** <<study title>>  
**Study Number:** <<protocol number>>  
**Sponsor:** <<sponsor>>  
**Study Doctor:** <<investigator>>  
<<firm name>>  
<<street address>>, <<city>>, <<state>> <<zip>>  
**Telephone Number:** <<000-000-0000>>  
**After Office Hours:** <<000-000-0000>>

The doctor wants to know if you want to be in a research study. This is because you have warts. The doctor wants to learn about a medicine that might help warts.

**Do I Have To Be In This Study?**

**You do not have to be in the study if you don't want to.**

This form explains the study. After reading this form, you can decide if you want to be in the study. Either choice is OK.

If you say you want to be in the study, you can change your mind later.

Please ask the doctor or nurse to explain anything you do not understand. They will answer all the questions you have.

You can ask questions about the study at any time. You can also talk to your parents and ask to read the information the doctor gives them.

**What is this Research Study about?**

The doctor is studying a medicine called A-101 Solution. The medicine will be put on the warts on your skin to see if the medicine is safe and helpful for children and adults who have warts.

The medicine is a liquid that goes on your warts.

In this study, some people will get A-101 Solution (liquid). Other people will get a liquid that looks like A-101 Solution but has no medicine in it.

You and the doctor cannot pick what you get. You and the doctor will not know what you get. This is because both liquids will look the same.

Using the liquid without medicine is the same as not using any medicine for your warts. Ask the doctor or nurse if you have any questions about this.

If you want to be in the study, here are things that will happen:

- If you are using any products for your warts, you have to stop using them.
- You will come to the doctor's office for up to 13 visits. The study lasts about 5 months.
- The doctor will give you a check-up.
- You will be asked about how you are feeling.
- You will be asked about any medicine you are taking.
- The doctor will look at your skin and see if you have warts that can be treated in the study. Then the doctor will choose up to 6 warts.
- Your parent or guardian will treat one or more of your warts with the medicine in front of the doctor.
- If the study doctor says it's OK, the warts may be treated at home by your parent or guardian.
- You will have pictures taken of your warts during the study.
- Blood samples will be taken from your arm with a needle.

The medicine being studied may or may not help your warts. You do not have to be in this study to get help with your warts. Talk to the study doctor about other things you can do for your warts.

**If you do not want to do any of these things, you can say you do not want to be in the study.**

### **Can anything bad happen to me in this study?**

The medicine may cause unwanted things to happen called side effects. Some side effects are not known yet. Here are some things that can happen to your skin when the medicine is put on your warts:

- Stinging or burning
- Itching
- Mild pain
- Redness
- Blistering of the skin
- The skin or hair might turn white where the medicine is put on.

You might also feel other things. While you are in the study, you have to tell the doctor or your mom or dad if you feel sick or if you take any medicines. You or your mom or dad can call the doctor.

### Could I be allergic to the medicine?

Sometimes people are allergic to medicine put on their skin. You could get a rash (red or rough skin) or feel other things where the medicine is put on your skin.

Tell your parents, guardian or the study doctor right away if you feel sick, or anything about you feels different.

Could I have problems if I get the liquid without medicine in it?

If you get the liquid without medicine in it, your warts could get worse. The liquid will not help you.

Could I have problems if I can't use my regular medicine?

You won't be able to use any other medicine on your warts while you are in the study. If you stop your regular medicine to be in the study, your warts might get worse. Please tell the doctor or nurse right away if you have any problems when you stop using your regular medicine.

Could I have problems from giving blood?

The doctor or nurse will take your blood with a needle. Some problems you might have from this are:

- pain
- bruising
- feeling dizzy
- infection at the place where the needle goes into your arm

**Who Can I Talk to About the Study?**

You can ask questions about the study any time. You can call the doctor any time. The doctor's phone number is on the first page.

If you want to ask questions about what it means to be in a research study, you or your parents can call Quorum Review at 1-888-776-9115 (toll free).

**Do you want to be in this study?**

Please sign below if you want to be in this study but remember: You don't have to be in this study if you don't want to.

\_\_\_\_\_  
Printed Name of Minor Participant

\_\_\_\_\_  
Signature of Minor Participant

\_\_\_\_\_  
Date

I attest that the minor participant named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

\_\_\_\_\_  
Printed Name of Person Explaining Assent

\_\_\_\_\_  
Signature of Person Explaining Assent

\_\_\_\_\_  
Date

I attest that I or my representative discussed this study with the minor participant named above.

\_\_\_\_\_  
Signature of Principal Investigator or Sub-Investigator